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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,661	05/26/2000	JEAN-PIERRE SACHETTO		6789

2292 7590 05/16/2005

BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/508,661	<b>Applicant(s)</b> SACHETTO ET AL.	
	<b>Examiner</b> Konata M. George	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33, 37, 46, 47, 49 and 51-56 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15, 22, 24-27, 38, 39 and 42 is/are rejected.
- 7) ☒ Claim(s) 3, 6, 43, 45, 48 and 50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*pd*

### **DETAILED ACTION**

Claims 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 are pending in this application.

### ***Action Summary***

1. The rejection of claims 22, 24-27, 33 and 46-55 under 35 U.S.C. 112, first paragraph is hereby withdrawn as applicant has removed the word "prophylaxis" from the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 22, 24-26 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Day (US 5,380,522).

Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art

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can be xanthan gum. It is the position of the examiner that when the composition is administered singly, the hydrophilic polymer would be the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach that the composition when prepared is in the form of a dry powder, which can be admixed with a fluid prior to ingestion. It is also the position of the examiner that the claimed disease states would be inherent as they are diseases that result from irritable bowel syndrome and thus be treated as a result of taking the composition.

3. Claims 27 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Sachetto (US 5,972,310).

Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in at a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e. H<sub>2</sub>O.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Day (US 5,380,522).

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Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art can be xanthan gum. It is the position of the examiner that when the composition is administered singly, the hydrophilic polymer would be the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach that the composition when prepared is in the form of a dry powder, which can be admixed with a fluid prior to ingestion. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg.

With respect to the claimed concentration, absent a clear showing of criticality, the determination of a particular concentration is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of treating inflammatory bowel disease.

5. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachetto (US 5,972,310).

Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in at a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e. H<sub>2</sub>O. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg.

With respect to the claimed concentration, absent a clear showing of criticality, the determination of a particular concentration is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of treating inflammatory bowel disease.

### ***Allowable Subject Matter***

6. Claims 3, 6, 43, 45, 48 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the composition containing hydroxypropylmethylcellulose as the sole therapeutically active agent. It is also not taught that the oral dosage form contains an enteric coating.

7. Claims 33, 37, 46, 47, 49 and 51-56 are allowed. The prior does not teach a composition containing hydroxypropylmethylcellulose as the sole therapeutically active agent.

### ***Conclusion***

8. Claims 1, 2, 15, 22, 24-27, 38, 39 and 42 stand rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is

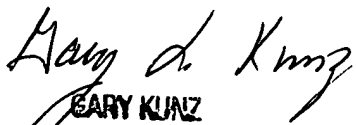
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(571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600